## **PCT**

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#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification: A1 (11) International Publication Number: WO 00/13615 A61F 2/28 (43) International Publication Date: 16 March 2000 (16.03.2000) (21) International Application Number: PCT/SE99/01576 Published (22) International Filing Date: 09 September 1999 (09.09.1999) (30) Priority Data: 9803078-6 09 September 1998 (09.09.1998) SE (60) Parent Application or Grant LANKA LIMITED [/]; (). BRUCE, Lars [/]; (). BRUCE, Ingrid [/]; (). BRUCE, Lars [/]; (). BRUCE, Ingrid [/]; (). AWAPATENT AB; ().

- (54) Title: IMPLANT, METHOD OF MAKING THE SAME AND USE OF THE SAME
- (54) Titre: IMPLANT, SON PROCEDE DE FABRICATION ET SON UTILISATION

#### (57) Abstract

An implant (prosthesis) comprising a batch of a mixture of porous grains/granular material of tissue-compatible type and disintegrated tissue-compatible biological material (preferably endogenous material, such as bone meal). The batch further comprises a component which allows moulding or modelling of the batch, and the batch is enclosed in a pouch or wrap made of a flexible tissue-compatible material and having pores/apertures/perforations or the like of a size which allows outgrowth and ingrowth of tissue of the biological material. The implant is applicable in many contexts, such as a fixing agent for a hip-bone prosthesis, as a filler in plastic surgery and as a bone growth promoting agent when treating rheumatism.

#### (57) Abrégé

Cette invention se rapporte à un implant (prothèse) comprenant une masse d'un mélange fait de grains poreux ou d'une substance granulaire poreuse du type compatible avec les tissus et d'une substance biologique désintégrée compatible avec les tissus (telle que de préférence une substance endogène, comme de la poudre d'os). Cette masse contient en outre un composant qui permet son moulage ou son modelage et ladite masse est enfermée dans une poche ou une enveloppe faite d'une substance souple compatible avec les tissus et présentant des pores/ouvertures/perforations ou similaires d'une grandeur permettant la croissance externe et la croissance interne des tissus de la substance biologique. Cet implant peut être utilisé dans un grand nombre d'applications, par exemple comme agent de fixation pour une prothèse de la hanche, comme charge en chirurgie plastique et comme agent favorisant la croissance osseuse lors du traitement des rhumatismes.

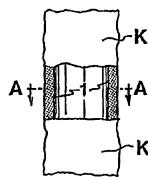
# **PCT**

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(51) International Patent Classification 7:		(1	1) International Publication Number:	WO 00/13615
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(21) International Application Number: PCT/SE (22) International Filing Date: 9 September 1999 (1) (30) Priority Data: 9803078-6 9 September 1998 (09,09.98) (71) Applicant (for all designated States except US): LIMITED [GB/GB]; Bourne House, 97 Woodbour Douglas, IM99 IBP (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): BRUCE, Lars P.O. Box 81, S-260 40 Viken (SE). BRUCE [SE/SE]; P.O. Box 81, S-260 40 Viken (SE). (74) Agent: AWAPATENT AB; P.O. Box 5117, S-200 1 (SE).	LANK THE ROS	SE (A ad,	(81) Designated States: AE, AL, AM, AZ, BA, BB, BG, BR, BY, CA (Utility model), DE, DE (Utility model), DM, EE, EE (Utility model), GB, GD, GE, GH, GM JP, KE, KG, KP, KR, KZ, LC. MD, MG, MK, MN, MW, MX, SD, SE, SG, SI, SK, SK (Utilit TT, UA, UG, US, UZ, VN, Y (GH, GM, KE, LS, MW, SD, S patent (AM, AZ, BY, KG, KZ, I) patent (AT, BE, CH, CY, DE, III, TT, LU, MC, NL, PT, SE), CG, CI, CM, GA, GN, GW, MI  Published  With international search report Before the expiration of the ti claims and to be republished in amendments.  In English translation (filed in S	, CH, CN, CR, CU, CZ, CZ y model), DK, DK (Utility model), ES, PI, FI (Utility I, HR, HU, ID, IL, IN, IS, LK, LR, LS, LT, LU, LV, NO, NZ, PL, PT, RO, RU, y model), SL, TJ, TM, TR, U, ZA, ZW, ARIPO patent SL, SZ, UG, ZW), Eurasian MD, RU, TJ, TM), European DK, ES, FI, FR, GB, GR, OAPI patent (BF, BJ, CF, L, MR, NE, SN, TD, TG).
(54) Title: IMPLANT, METHOD OF MAKING THE SA (57) Abstract	ME A	.ND	USE OF THE SAME	
An implant (prosthesis) comprising a batch of a mixt material of tissue-compatible type and disintegrated t material (preferably endogenous material, such as bone comprises a component which allows moulding or modelling	issue-c meal)	com	patible biological The batch further	K

An implant (prosthesis) comprising a batch of a mixture of porous grains/granular material of tissue-compatible tological material (preferably endogenous material, such as bone meal). The batch further comprises a component which allows moulding or modelling of the batch, and the batch is enclosed in a pouch or wrap made of a flexible tissue-compatible material and having pores/apertures/perforations or the like of a size which allows outgrowth and ingrowth of tissue of the biological material. The implant is applicable in many contexts, such as a fixing agent for a hip-bone prosthesis, as a filler in plastic surgery and as a bone growth promoting agent when treating theumatism.



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## Description

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### IMPLANT, METHOD OF MAKING THE SAME AND USE OF THE SAME

The present invention relates to an implant and a method of making the same and use of the same.

US-A-5,217,496 (Bruce) discloses an implant (prosthesis) comprising a layer of a mixture of pulverulent material of tissue-compatible type and disintegrated tissue-compatible biological material which, by adding a nutrient solution, has been allowed to grow and link the components of the mixture to each other. This patent publication also discloses a method of making such an implant using a mould.

US-A-5,015,256 (Bruce) discloses a means for fixing in a cementless manner a joint prosthesis, comprising a biological compatible granular material of essentially irregular, porous and plastic grains having a size of less than 5 mm. For fixing of the joint prosthesis, the means is inserted into the cavity in which the prosthesis is to be fixed, and the prosthesis is driven into the means and the cavity during vibration of the grains. The vibration causes the grains to be packed in the cavity between prosthesis and cavity wall during interlocking and locking of the prosthesis in the cavity. The mass or bed of the material may contain grains of endogenous material.

Experiments carried out using the above-described fixing technique have proved that a particularly quick and stable, permanent and painless fixing (healing) of prosthesis is achieved precisely if the granular material comprises endogenous material formed of tissue of the same type in/against which the implant is to be inserted or placed, respectively, for instance bone tissue from the femoral cavity if the prosthesis to be fixed is a femoral prosthesis. The bone tissue forms bone (cells) enclosing the grains and extending from the wall

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of the cavity to the prosthesis. Moreover, these experiments have shown that the more linked grains of material (plus endogenous material), the guicker fixing of the prosthesis. It seems as if the tendency of the body cells 5 to grow increases the shorter the distance between the grains.

The invention is based on the teachings of the known techniques as described above and of the above-mentioned experiments. The knowledge on which the invention is based thus is that the grains of material must be linked to each other and preferably compacted, and that endogenous biological material, tissue, and nutriment should be available in the material or should have the possibility of penetrating the same.

One could say that the body cavity in US-A-5,015,256 constitutes the mould in the method according to US-A-5,217,496 and comprises natural nutrient solution for cell growth, viz. endogenous body fluid, such as blood.

US-4,755,184 discloses an implant in the form of a sausage, the casing of which consists of a porous hose tied at the ends and containing hydroxyapatite. The casing is firmly packed.

According to the invention, the implant comprises a batch of a mixture of porous grains/granules of tissuecompatible type and of disintegrated tissue-compatible biological material, preferably endogenous tissue and preferably endogenous tissue from the location of the implant, said batch further comprising one more component which makes the batch capable of being moulded or model-30 led, said batch being enclosed in a pouch or a wrap of a tissue-compatible, flexible sheet, foil, woven fabric, or the like with apertures/perforations/meshes which are permeable for tissue growth from inside the pouch/wrap to the surroundings and from outside into the pouch. The . 35 batch must be well kept together and preferably compacted in the pouch/wrap. The latter should be closed, for

example sewn together so that no grains/granules can

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leave the pouch/wrap. The pouch/wrap may consist of, for instance, gauze bandage.

The preferably performed packing of the batch in the pouch/wrap is carried out to a degree of packing which is necessary for the purpose of the implant. If the purpose of the implant is to support parts of the body or keep a distance between parts of the body, such as vertebrac, the degree of packing must be greater, i.e. be capable of having a supporting and spacing function, than in the case where it is a matter of filling a cavity in the body, such as for plastic surgical purposes, and other purposes if it is a matter of bone growth promoting agent for rheumatics.

The compacting of the batch in the pouch/wrap can advantageously be performed by vibration. Vibration produces the further advantage that the components of the batch are adequately mixed and that nutrient penetrates into the pores of the grains/granules, which is advantageous. Vibration can take place at a certain higher frequency for mixing and another lower frequency for compacting. For vibration, use can be made of e.g. ultrasounce.

Nutrient can be added to the batch in vitro, for example by lowering the pouch with the batch into a conventional nutrient solution or blood/plasma and vibrating the pouch, through the wall apertures of which the nutrient reaches the batch to provide tissue growth. However, nutrient can also be added to the batch in vivo, at the location of the implant, which then contains endogenous fluids which can penetrate the pouch.

According to the purpose of application, the implant can be sewn, nailed etc. to the location of the implant in/on the body, which can be necessary when the implant fills a cavity in the body and there is a risk of dislocation. However, if the implant can be expected to be fixed by wedging, such as between vertebrae, no specific fixing means need be used.

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The implant is formed during compacting to a shape which well fills the cavity, the space or the distance where it is to be inserted. This is important since otherwise (distance between body tissue and pouch) there is a risk that the implant does not grow on or that connective tissue forms between pouch and body tissue.

It would have become apparent that the shape of the implant according to the invention may be arbitrary, such as a flat plate, a piece of strip, a cylinder, a rod etc.

The pouch containing said mixture can be shaped by using a further/some further tissue-compatible components in the batch which make the batch kneadable and retain the shape of the pouch/wrap caused by the kneading. A suitable component is a hardenable two-component fibrin adhesive which is available on the market, such as from IMMUNO (Schweiz) AG. A further suitable component is FocalSeal (registered trademark), a surgical sealing agent marketed by Focal, Inc. USA. However, it should be emphasised that blood (which contains fibrin and coagulates) in itself is a suitable further component which allows moulding of the mixture in or outside the pouch/ wrap to the form of a cavity, to the form of which the implant is to be fitted. As a pattern for the moulding or modelling, use can be made of, for example, an X-ray recording of the body cavity in question.

When considered convenient, the pouch/wrap may be made of a resorbable material. One example is SURGICEL (TM) from ETHICON LTD.

As material for the tissue-compatible grains/granules, it is possible to select according to the invention first of all titanium, but also other materials are suited, which are known to the skilled person for the purpose, such as bioceramics, bioglass, hydroxyapatite, polymers, dextran. Porous grains/granules which are not porous by nature, such as titanium, are obtained in prior-art manner by blowing gas or liquid through a melt of the material.

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5 Ε, The grains/granules have an essentially uniform particle size distribution, preferably plastic and irregular. The reason for this is that, when interlocking and 10 compacting by vibration, different particle sizes should not be arranged in layers in the body cavity with the ensuing risk of irregular and thus impaired tissue growth. By an essentially uniform particle size distribu-15 tion is meant that the grain/granule diameter may vary by  $\pm$  50%, preferably by  $\pm$  25% or less. The absolute size of the grains/granules may vary in relatively wide ranges, a grain/granule size below 5 mm being considered most convenient. The lower limit may be difficult to estab-20 lish, and it would be possible to use very small grain particles in combination with a biocompatible liquid 15 which forms the small particles (dust). However, grains/ granules above 0.1 mm are normally used. Preferably, the 25 upper limit may be about 2 mm and the lower limit 0.5 mm. It may be generally said that the grain/granule size is selected in consideration of the space which after com-20 pleted surgery should be packed with grains/granules, 30 i.e. larger grains/granules can be selected for larger body cavities than for small ones. The terms "grains/ granules", "irregular" and "diameter" cover other forms than (approximately) spherical. 35 25 If the implant according to the invention is to be used for replacement or repair of bone tissue, the grains/granules most preferably consist of plastic or not essentially elastic, continuously porous biocompat-40 ible material, preferably metal or metal alloy, such as titanium, having the following porosity characteristics: - the porosity is continuous - the opening of pits/indentations/pockets and the 45 channels/passages interconnecting the same has a width of > about 50  $\mu m$  for bone tissue. Such a porosity results in voids in the grains which are interconnected by channels,

passages, so that growth of bone tissue to a part of the

outer surface of the grains allows the growth to continue

5 6 through individual grains and out through other parts of the outer surface of the grains. According to the invention, the mixing of the batch components to provide the above-mentioned batch can be 10 carried out before introducing the batches into the pouch or before wrapping the batches. In this connection, a batch of nutrient is added to the mixture. Alternatively, and still according to the invention, the mixing can be 15 carried out after introduction into the pouch or after wrapping the batches. In, for instance, surgery on the spinal column for replacing worn-out intervertebral discs between verte-20 brae, use is often made of implants that are screwed between the vertebrae. Such implants are rigid and may contain bone fragments, see US-A-4,501,269 and US-A-15 5,489,308. Such bone fragments are, however, not avail-25 able in a sufficient quantity, and it is the implants that have the supporting function and may cause pain. Such implants are also complicated and expensive to manufacture. 20 30 The invention remedies this and suggests an implant of the type described above for stabilising the spinal column. Fig. 1 is a schematic view of two annular-cylindri-35 cal pouches 1 having contents as described above and being inserted between two vertebrae K. The pouches 1 are well filled with the batch (the grains/granular material is made of titanium), which has been vibrated for ade-40 quate mixing and compacting so that the distance between 30 the vertebrae can be kept correct. Bone forms rapidly and takes over the supporting function. The pouches are made of the above-described, exemplifying resorbable material. 45 Fig. la is a sectional view a-a. Fig. 2 illustrates an implant 2 according to the . 35 invention inserted in a hip-bone cavity S for fixing a

hip-bone implant 3 in the hip-bone cavity, said hip-bone

\*implant 3 consisting of a conventional plastic cup 4

10	5	coated with titanium 5 and resting on, with a press fi a thin pouch 1 formed according to the hip-bone cavity and containing the above-described batch in which the grains/granules consist of titanium. The pouch 1 is al made of the described, exemplifying resorbable materia in the form of a woven fabric.  In one more embodiment of the invention, the inte	.so
15	10	rior chamber in a spinal column implant is of the type described in, for instance, US-A-5,015,247 and US-A-4,501,269 filled with an implant according to the invetion.	2
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## Claims

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#### PMT 4.10

		CHAINS
10		1. An implant (prosthesis) comprising a batch of
	. 5	a mixture of porous grains/granular material of tissue-
		compatible type and disintegrated tissue-compatible bio-
		logical material (preferably endogenous material such as
15		bone meal), characterised in that the batch
		comprises one more tissue-biocompatible component which
	10	allows modelling or moulding of the batch, and that the
		batch is enclosed in a pouch or wrap made of a flexible
20		tissue-compatible material and having pores/apertures/
		perforations or the like of a size which allows ingrowth
		and outgrowth of tissue of the biological material.
	15	2. An implant as claimed in claim 1, charac-
25		terised in that the flexible material is one of
		resorbable woven fabric, for instance regenerated cel-
•	•	lulose or polymer.
	•	3. An implant as claimed in claim 1 or 2, char-
30	20	acterised in that the grains/granular material
		consists of titanium or polymer or dextran.
		4. An implant as claimed in any one of claims 1-3,
		characterised in that the batch comprises a
35		nutrient/nutrient solution of a kind that promotes
-	25	growth of the tissue-compatible biological material in
		the batch.
		<ol><li>An implant as claimed in any one of claims 1-4,</li></ol>
40	* .	characterised in that the further component i
TV.		a hardenable component and a hardening agent therefor.
	30	6. An implant as claimed in any one of claims 1-5,

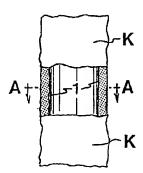
characterised in that the further component is blood.

7. An implant as claimed in any one of claims 1-6, characterised in that the size of the grains/  $\,$  35  $\,$  granules is between 0.1 and 5 mm, preferably 0.5-2 mm.

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		8. An implant as claimed in any one of claims 1-7,
		characterised in that the batch of grains/
		granules is compacted in the pouch/wrap.
10		9. An implant as claimed in any one of claims 1-8,
	s	characterised in that the grains/granules are
		plastic or not essentially elastic as well as porous hav-
		ing the following porosity characteristics:
15		- the porosity is continuous
		- the opening of pits/indentations/pockets and the
	10	channels/passages interconnecting the same has a width of
		> about 50 $\mu m$ for bone tissue.
20		10. Use of an implant as claimed in any one of
		claims 1-9 as an intervertebral prosthesis.
		11. Use of an implant as claimed in any one of
	15	claims 1-9 as a fixing agent for a hip-joint prosthesis.
25		12. Use of an implant as claimed in any one of
		claims 1-9 as a filler in, for instance, plastic surgery.
•		13. Use of an implant as claimed in any one of
		claims 1-9 as a bone growth promoting agent when treating
30	20	rheumatism.
		14. Use of an implant as claimed in any one of
		claims 1-9 as filling in body cavities, pits, indenta-
		tions and the like, or as a carrier between parts of the
35		body, such as between vertebrae.
	25	15. Use of an implant as claimed in any one of
		claims 1-9 as a spacer in the body.
		16. Use of an implant as claimed in any one of
40		claims 1-9 as reinforcement of defective/removed tissue.
	20	17. Use of an implant as claimed in any one of
	30	claims 1-9 as tissue (bone) replacement.
		18. Use of an implant as claimed in any one of
45		claims 1-9 complementary to conventional implants.

FIGI



FIGIa

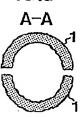
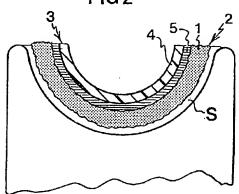


FIG 2



## INTERNATIONAL SEARCH REPORT

International application No.

			PCT/SE 99/0	1576				
A. CLAS	SIFICATION OF SUBJECT MATTER							
According t	A61F 2/28 o International Patent Classification (IPC) or to both no	uional classification and	IPC					
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Electronic d	ata base consulted during the international search (name	of data base and, when	e practicable, scarch	terms used)				
c. Docu	MENTS CONSIDERED TO BE RELEVANT							
Category*	Citation of document, with indication, where ap	propriate, of the relo	ant passages	Relevant to claim No.				
A,	US 5217496 A (LARS BRUCE ET AL) (08.06.93)	, 8 June 1993		1-7,9-10,12, 14-16				
	<del></del>							
A	US 4755184 A (MARK SILVERBERG), 5 July 1988 1-7,9-1 (05.07.88), column 1, line 58 - line 60; column 3, line 37 - line 48							
A	US 5015256 A (INGRID BRUCE ET AL (14.05.91)	.), 14 May 19	91	1-16				
	<del></del>							
A	US 5571189 A (STEPHEN D. KUSLICH (05.11.96)	H), 5 November	1996	1-16				
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X Furth	er documents are listed in the continuation of Box	x C. X See p	atent family annex					
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the priority date claimed "&" document member of the same patent family								
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# INTERNATIONAL SEARCH REPORT

International application No.
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		PCT/SE 99/0157	b
C (Continu	ation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant	ant passages Re	levant to claim No
A	GB 2259252 A (TORAO OHTSUKA), 10 March 1993 (10.03.93), abstract		1-16
A	EP 0709070 A2 (OSTEONICS CORP.), 1 May 1996 (01.05.96), column 4, line 24 - line 26, f	igure 5	1-16
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## INTERNATIONAL SEARCH REPORT

International application No. PCT/SE9901576

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Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This into	rnational search report has not been established in respect of certain claims under Article 17(2Xa) for the following reasons:
1. 🖾	Claims Nos: 10-18 because they relate to subject matter not required to be searched by this Authority, namely:  Remark: Although claims 10-18 is directed to a method of treatment of the human/animal body, the search has been carried out based on the alleged use of the device.
2.	Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Box II	
	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)  rnational Searching Authority found multiple inventions in this international application, as follows:
L	As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	on Protest The additional search fees were accompanied by the applicant's protest.
	No protest accompanied the payment of additional search fees.

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# INTERNATIONAL SEARCH REPORT Information on patent family members

International application No. PCT/SE 99/01576

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(54) Title: INTERVERTEBRAL SPACERS WITH SIDE WALL ACCESSIBLE INTERIOR CAVITY

(54) Titre: ESPACEURS INTERVERTEBRAUX A CAVITE INTERIEURE ACCESSIBLE PAR UNE PAROI LATERALE

#### (57) Abstract

Intervertebral spacers, tools for implanting intervertebral spacers and methods of promoting fusion bone growth in the space between adjacent vertebrae are provided. The spacers include an elongated body having a first end, a second end and an outer surface. Side walls connect the first and second ends. The elongated body also defines an interior cavity. The side wall defines an opening to the interior cavity in a side of the elongated body. At least one of the first and second ends has a discontinuity, such as a concave surface, for nesting with an adjacent spacer. The tools include spacer engaging means for engaging a spacer and occlusion means for blocking an opening defined in the spacer. In some embodiments, the occlusion means includes a plate extendible from the housing. In one specific embodiment the plate defines a groove which is disposed around a fastener attached to the housing so that the plate is slideable relative to the housing. The methods of promoting fusion bone growth include utilizing the inventive spacers described herein.

#### (57) Abrégé

L'invention concerne des espaceurs intervertébraux, des outils permettant d'installer ces espaceurs, et des techniques favorisant la croissance osseuse par fusionnement dans l'espace situé entre des vertèbres adjacentes. Ces espaceurs comprennent un corps allongé possédant une première extrémité, une seconde extrémité, et une surface extérieure. Les parois latérales relient les première et seconde extrémités. Le corps allongé définit également une cavité intérieure. Lesdites parois latérales définissent une ouverture vers la cavité intérieure, sur un côté du corps allongé. Au moins l'une des première et seconde extrémité présente une discontinuité, telle qu'une surface convexe, destinée à s'emboîter dans un espaceur adjacent. Les outils comprennent un organe d'engagement d'espaceur qui permet d'engager ledit espaceur, et un organe d'occlusion qui bloque une ouverture définie dans l'espaceur. Selon certains modes de réalisation, l'organe d'occlusion comprend une plaque extensible à partir du logement. Selon un mode de réalisation spécifique, la plaque définit une rainure entourant un système de fixation fixé au logement, de sorte que ladite plaque peut coulisser par rapport à ce dernier. Les techniques favorisant la croissance osseuse par fusionnement consistent à utiliser les espaceurs de cette invention.